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March 2, 1995

Mr. Gary Dykstra
Food and Drug Administration
Washington, D.C.

Re: Notice of a new statement of nutritional support for our Opti-Packs,
a multi-vitamin/multi-mineral daily supplement in packets.

Reference: Public Law 103-417, Sec. 6, (A), (B) & (C), Statements of
Nutritional Support

Dear Mr. Dykstra,

I am sending this notice to you because I don't know where else in FDA to send such a notice. You may remember me; you invited me, as James Coburn's *in-absentia* delegate, to meet with you, Carol Scheman, Mary Pendergast and three others in November, 1992 in the matter of the letter that James Coburn sent to then-President Bush.

Because FDA has not yet promulgated regulations re Public Law 103-417, specifically re Statements of Nutritional Support, and because my company has begun using 2 new advertising pieces in which are mentioned three points which I feel may be included as points in Section 6 of the Public law referenced above, I am submitting notice to FDA of the marketing of our product using those points in our statements.

Point #1. Use of the term, *Anti-aging vitamins*

Point #2 Use of the term, *Premature Aging*

Point #3. Use of the reference to possible improved health and improved function resulting from use of the product, and our accompanying guarantee that if improved health doesn't follow, money will be refunded.

Although we have been marketing our Opti-Packs since 1979, we have only begun marketing Opti-Packs with the new accompanying statements since February 5, 1995. In line with Section 6 of Public Law 103-417, I am notifying you of the new statements, now accompanying this product, as the law directs, within 30 days of commencing sales. Although I am not sure if this is called for yet (or should be delayed until promulgation of FDA's regulations for Public Law 103-417), I want to make the attempt to comply with the law as soon as possible. And I wish to comment below on our use of the three points mentioned above.

I realize this may be premature but you may know that I have a high profile in the dietary supplement industry and, in line with our

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November, 1992 conversations about my feelings that the industry and FDA should work more closely together, I want to take this opportunity to set an example of prompt compliance with the new law for others in the industry.

You will see that there are two statements enclosed which are designed to accompany the Opti-Packs. The first is the statement on the enclosed poster; the second is the statement in the accompanying brochure.

You will also see that after the heading, "Anti-Aging Vitamins", on the poster, there is an asterisk which refers to the very prominent statement on the left edge of the poster. You will see that at the top of the statement, there is a "disclaimer", explaining that anti-aging vitamins are "to help slow or even prevent premature aging from nutritional deficiencies and nutrient-depleting life-stresses". The rest of the statement discusses "premature aging", with the intent to clearly state that preventing "premature aging" is a possibility if the premature aging is from nutritional deficiencies or life-events that deplete nutrients.

The accompanying brochure elaborates on this statement by including life-style modifications that are known to favorably impact nutrition (specifically at the cellular level, where all nutrition ultimately "ends up" and acts). My intent was to make it very clear that supplementation is not a "magic bullet" but rather just one of the many possible life-style steps one may take to help ensure properly functioning overall metabolism, and thus overall health and function.

As you may remember from our conversation at FDA in November, 1992, that I am a researcher whose goal it is to promulgate information that there are many ways for individuals to achieve improved overall well-being, dietary supplements merely being one way to help ensure optimum nutrition.

Attached you will find referenced a series of scientific articles which state that it is known that both nutritional deficiencies (frank, marginal, hidden or overt) and life-style stresses can accelerate the "normal aging" process, resulting in an "accelerated" aging (which I refer to as "premature aging"). You will find references which state that both health and overall function have been shown to be improved by supplying deficient nutrients. And you will see that the statements accompanying the Opti-Pack are all clearly conditional, and refer to the taking of supplements as nutritional insurance against the possibility of hidden, overt, frank or marginal nutritional deficiencies.

Finally, I want you to know that, as I indicated to you at our November, 1992 meeting, that I do not have a contentious banner to bear in any way. I do not want to change laws or circumvent FDA

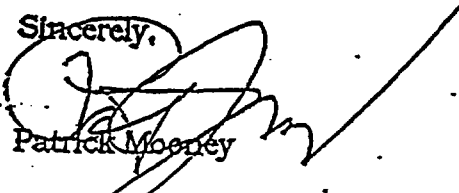
regulations. I recognize that FDA has its duties and when I began this business in 1977, commitment to compliance with FDA regulations was just one detail in many in planning a business supplying dietary supplements (as were commitments to compliance with local building department regulations and commitment to compliance with postal regulations). I do not want to make claims about curing, preventing, mitigating or ameliorating any diseases. I do believe that stabilized or improved metabolism (thus health) is a highly probable result of life-style modifications in the five areas mentioned in the accompanying brochure, and I merely want to present to the public the alternative to use this balance and potency of supplements. I use this terminology to communicate this information, along with quite extensive disclaimers, so as not to mislead the public.

If FDA finds the manner in which I have done this not in compliance with Public Law 103-417, I will gladly withdraw or modify the statements as necessary. Over the years that I have been in business, I have been as judicious as possible about claims. I have no desire to make claims or step outside the bounds (1) of the laws governing supplement manufacture and sales, or (2) of FDA regulations associated with those laws. In fact, on occasions I have presented my dietary supplement formulas to FDA to evaluate (in terms of FDA issuing a statement of Free Sale for foreign countries). Further, I am in regular contact with my local FDA office in San Francisco, conferring with Mr. McCormick whenever I am in doubt about an FDA regulation. In other words, I am not looking for trouble; I just want to disseminate information and supplements within the regulatory framework of FDA. And, finally, as an encouragement toward acceptability of my terminology, I have noticed the frequent use of the term "anti-aging" in reference to several face creams and treatments advertised on national television (accompanied, I assume, by proper disclaimers on the labels).

I mention this so that you will recognize me as non-contentious and willing to work within the framework that FDA determines for enforcement of Public Law 103-417. So, since regulations about this matter have not yet promulgated, I am asking: Is this O.K.? Have I referenced my statements adequately? What are your recommendations?

I realize that you most probably will forward this to the proper division of FDA and I look forward to FDA's response.

Sincerely,


Patrick Mooney

Enclosures: Poster, Brochure, Scientific References (5 pages)

Addendum to Supernutrition Life-Extension Research letter to FDA of 3/2/95

The following is a rationale, using scientific references, for the use of the terms, "Anti-Aging Vitamins" and "premature aging", and for use of the statements that "anti-aging vitamins" may help prevent some "premature aging" if the premature aging is associated with nutritional deficiencies or lifestyle habits or events that deplete nutrients.

POSTULATE 1: RE USE OF THE TERM "PREMATURE AGING",
VARIATIONS IN AGING RATES INCLUDE,

- "SUCCESSFUL" AGING ("SLOWED" AGING)
- "NORMAL" AGING ("USUAL" AGING)
- "UNSUCCESSFUL" AGING ("PREMATURE" AGING)

References: (A summary sentence or a quotation, followed by the referenced article or book)

Physiological aging does not necessarily parallel chronological aging.

Vestal, Robert E., and Cusack, Barry J., *Pharmacology and Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 349.*

In a population, there are individuals with "successful aging", others with "usual aging", thus, there are others with "unsuccessful aging".

Rowe, J. W., & Kahn, R. L., *Human aging: Usual and successful Aging. Science, 1987, 237, 143-149*

Many geriatricians believe that normal aging is a non-pathological process. It is likely that unrecognized illnesses and accumulated untreated injuries are responsible for much of the pathology attributed to "aging"

Horvath, Thomas B., and Davis, Kenneth L., *Central Nervous System Disorders in Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 306.*
(This reference also included in Postulate 2 references.)

Individuals with high levels of risk factors for mortality will have shortened lifespans.

Rowe, John W., Wang, San Y., and Elahi, Dariush. *Design, Conduct, and Analysis of Human Aging Research, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 64*

Reversible pathological lesions to the central nervous system leading to decline in function should be separated from "the truly irreversible accompaniments of aging".

Horvath, Thomas B., and Davis, Kenneth L., *Central Nervous System Disorders in Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 325.*

Physiological state may be influenced by temperature and nutritional state.

Howard, E. A., & Blackburn, E. H. *Reproducible and variable genomic arrangements occur in the developing somatic nucleus of the ciliate, Tetrahymena thermophila. Molecular and Cellular Biology, 1985, 5, 2039-2050*

Pure aging can be separated from temporal aging influences, including educational, nutritional, environmental and other influences.

Elahi, V. K., Elahi, D., Andres, R., Tobin, J. D., Butler, M. G., & Norris, A. H., *A longitudinal study of nutritional uptake in men. Journal of Gerontology, 1983, 38, 162-180.*
(This reference also included in Postulate 2 references.)

Thus we use the term "premature aging" to denote aging that is not identical with what is commonly termed normal aging, and that "premature" aging is, in fact, aging accelerated by "outside causes", such as disease states, nutritional deficiencies, stressful lifestyle habits (such as not exercising, smoking cigarettes), an imbalanced diets (such as eating a very high-fat diet).

POSTULATE 2: NUTRITIONAL DEFICIENCIES AND VARIOUS LIFESTYLE STRESSES CAN ACCELERATE "USUAL" AGING THUS CONVERTING IT TO "PREMATURE AGING".

References:

"With the passage of time over the adult age period, profound changes in appearance and function occur in all organisms. These result from the combined influences of life-style, nutrition, state of physical conditioning, and disease, all of which are superimposed on what is commonly referred to as the 'aging process'."

Lakatta, Edward G., *Heart and Circulation, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 181.*

Pure aging can be separated from temporal aging influences, including educational, nutritional, environmental and other influences.

Elahi, V. K., Elahi, D., Andres, R., Tobin, J. D., Butler, M. G., & Norris, A. H., *A longitudinal study of nutritional uptake in men. Journal of Gerontology, 1983, 38, 162-180.*

(This reference also included in Postulate 1 references.)

Many geriatricians believe that normal aging is a non-pathological process. It is likely that unrecognized illnesses and accumulated untreated injuries are responsible for much of the pathology attributed to "aging"

Horvath, Thomas B., and Davis, Kenneth L., *Central Nervous System Disorders in Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 306.*

(This reference also included in Postulate 1 references.)

"Physiological function decreases with age and there is evidence that eventual physical deterioration in some organs may be associated with diet earlier in life."

Ausman, Lynne M., & Russell, Robert M., *Nutrition and Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 384.*

Physical conditioning will influence (slow down) age-related declines in cardiovascular performance. Lack of physical conditioning will also influence (accentuate, accelerate) age-related declines in cardiovascular performance.

Lakatta, Edward G., *Heart and Circulation, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 182.*

(This reference also included in Postulate 3 references.)

The composition of dietary fat of animals diets and the amounts of dietary antioxidants influence lifespan. High-fats diets are associated with shortened lifespans.

Reddy, B. S., Marisawa, T., Vakisich, D., Weisburger, J. H., & Wynder, E., *Effect of quality and quantity of dietary fat and dimethylhydrazine in colon carcinogenesis in rats. Proceedings of the society for Experimental Biologic and Medicine. 1976, 151, 237-239.*

"Thus the osteopenia associated with aging in women is not only due to estrogen deficiency, but represents a condition which is affected by numerous life-style habits and disease processes."

Goldberg, Andrew P. & Hagberg, James, *Physical Exercise in the Elderly, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 421.*

"In the elderly, vitamin deficiency, particularly with ascorbic acid, is associated with reduced (antipyramine) metabolism, which is increased after vitamin supplementation."

Smithard, J., & Landman, M. J. S., *The effect of vitamin supplementation upon antipyramine metabolism in the elderly. British Journal of Clinical Pharmacology, 1978, 5, 181-185.*

(This reference also included in Postulate 3 references.)

"Accelerated aging may be caused by environmental insults such as poor diet, smoking, excess drinking, or inadequate exercise."

Dean, Ward, M.D., *Biological Aging Measurement - Clinical Applications, The Center for Bio-Gerontology, Los Angeles, 1988, 6.*

"However, it is apparent that age-dependent alterations in biochemical and physiological functions are not only the result of well-defined molecular changes, but are also consequences of multiple and complex disturbances in a variety of regulatory systems."

Roch, George S., *Age-related changes in hormone action: The role of receptors, Biological Mechanisms in Aging, Conference Proceedings, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, June 1980, 691.*

Impaired cognition, previously having been attributed to aging is being shown to be disease-related.

Research Advances in Aging 1984-1986, U.S. Department of Health and Human Services, Public Health Service, National Institute of Health, 5.

Dementia of aging may be accelerated by a number of factors, including disease states such as Alzheimer's disease, multiple infarcts, chronic alcohol toxicity, affective illness, metabolic disturbances/nutritional deficiency, and degenerative diseases.

Horvath, Thomas B., and Davis, Kenneth L., *Central Nervous System Disorders in Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 312.*

Differences in habits, such as use of alcohol, caffeine, or tobacco might introduce apparent age effects by modifying the individual's metabolism. Other variables include: (antecedent) diet, activity, exercise status, body composition, and psychological and socio-economic factors.

Rowe, John W., Wang, San Y., and Elahi, Dariush. *Design, Conduct, and Analysis of Human Aging Research, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 68.*

POSTULATE 3: SUPPLYING DEFICIENT NUTRIENTS AND MODIFYING STRESSFUL LIFE-STYLE HABITS CAN SLOW DOWN AN ACCELERATED AGING PROCESS AND/OR PROTECT AGAINST ACCELERATED AGING.

References:

Physical conditioning will influence (slow down) age-related declines in cardiovascular performance. Lack of physical conditioning will also influence (accentuate, accelerate) age-related declines in cardiovascular performance.

Lakatta, Edward G., *Heart and Circulation, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 182.*

(This reference also included in Postulate 2 references.)

Modification of nutrition, an increase in physical activity, or other life-style modifications may be an influence in preventing or reversing diminution in cardiovascular function.

Lakatta, Edward G., *Heart and Circulation, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 209.*

Adding various antioxidants to the diet increases the lifespan of mice, rats, fruit flies and nematodes; inhibits the development of some forms of cancer; enhances humoral and cell-mediated immune responses; and slows the development of autoimmune disorders.

Dean, Ward, M.D., *Biological Aging Measurement - Clinical Applications, The Center for Bio-Gerontology, Los Angeles, 1988, 245.*

The aging process of rodents may be retarded, by dietary manipulation, thus increasing maximal life span.

McCarter, R., Masoro, E. J. & Yu, B. P., *Does food restriction retard aging by reducing the metabolic rate? American Journal of Physiology, 1985, 248, E488-490.*

Calcium supplementation in rats improved old rats performance on certain tests involving learning.

Research Advances in Aging 1984-1986, U.S. Department of Health and Human Services, Public Health Service, National Institute of Health, 5.

"In the elderly, vitamin deficiency, particularly with ascorbic acid, is associated with reduced (antipyramine) metabolism, which is increased after vitamin supplementation."

Smithard, J., & Landman, M. J. S., *The effect of vitamin supplementation upon antipyramine metabolism in the elderly. British Journal of Clinical Pharmacology, 1978, 5, 181-185.* (This reference also included in Postulate 2 references.)

"The provision of adequate nutrition to the elderly is important, as in other age groups, to prevent deficiency diseases, to delay degenerative changes, and to serve as a reserve in the event of stress."

Ausman, Lynne M., & Russell, Robert M., *Nutrition and Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 384.*

Zinc supplements have been shown to boost immune function in older people.

Research Advances in Aging 1984-1986, U.S. Department of Health and Human Services, Public Health Service, National Institute of Health, 13.

"Lifelong intake of calcium is widely thought to influence the amount of osteoporosis in the elderly."

Ausman, Lynne M., & Russell, Robert M., *Nutrition and Aging, Handbook of the Biology of Aging, Third Edition, Academic Press, 1990, 393.*

"In recent surveys, up to 15 percent of the elderly had elevated homocysteine levels, which went back to normal when the mild deficiencies were corrected."

Evans, William, Ph.D., & Rosenberg, Irwin, H., M.D., with Jacqueline Thompson, at the U.S. Department of Agriculture's Human Nutrition Center on Aging at Tufts University, *Biomarkers, Simon & Schuster, New York, 15.*

"Perhaps the most startling finding was the 70-year-olds who followed all these health rules were as healthy as people, aged 35 to 44, who practiced only three."

Evans, William, Ph.D., & Rosenberg, Irwin, H., M.D., with Jacqueline Thompson, at the U.S. Department of Agriculture's Human Nutrition Center on Aging at Tufts University, *Biomarkers, Simon & Schuster, New York, 259.*

"Advanced age is not a static, irreversible biological condition of unwavering decrepitude. Rather, it is a dynamic state that, in most people, can be changed for the better no matter how many years they've lived or neglected their body in the past.....The 'markers' of biological aging can be more than altered: in the case of specific physiological functions, they can actually be reversed."

Evans, William, Ph.D., & Rosenberg, Irwin, H., M.D., with Jacqueline Thompson, at the U.S. Department of Agriculture's Human Nutrition Center on Aging at Tufts University, *Biomarkers, Simon & Schuster, New York, 15.*

"At the Human Nutrition Research Center on Aging, we've shown that supplementing elderly people's diet with Vitamin E, an antioxidant nutrient, for one month improves their immune responsiveness.....What we need now is more conclusive evidence that (dietary antioxidants) can counteract some of the age-related decline in the immune system."

Evans, William, Ph.D., & Rosenberg, Irwin, H., M.D., with Jacqueline Thompson, at the U.S. Department of Agriculture's Human Nutrition Center on Aging at Tufts University, *Biomarkers, Simon & Schuster, New York, 250.*

In 20 cited studies, intervention with antioxidants, Vitamin E and other dietary supplements have been shown to prolong lifespan in laboratory animals and in some cases to prevent or delay age-related changes.

Finch, Caleb E. & Schneider, Edward L., *Handbook of the Biology of Aging, Second Edition, Van Nostrand Reinhold Company, New York, 1985, 68.*

"It is becoming increasingly apparent that there may be multiple mechanisms for aging, thus making segmental interventions, which alter some physiological parameters without effecting others, the most plausible and potentially rewarding interventions."

Schneider, Edward L., Reff, Mitchell E., Finch, Caleb E., Weksler, Marc, *Potential application of biological markers for assessing interventions of physiological aging*, 237. *Biological Markers of Aging*, U.S. Department of Health and Human Services, National Institutes of Health, Public Health Service, NIH Publications No. 82-2221, April 1982, 237.

"At present, the most accepted means to retard aging and the development of age-related pathology are: (1) caloric restriction; (2) administration of anti-oxidants; and (3) physical exercise."

Dilman, Vladimir, M.D., Ph.D., D.M.Sc. & Dean, Ward, M.D., *The Neuroendocrine Theory of Aging and Degenerative Disease*, Center for Bio-Gerontology (Press), Pensacola, Florida, 1992, 9.

RE: COMPLYING WITH PUBLIC LAW 103-417, PGPH (B).

POINT 1 - THAT "THE STATEMENT IS TRUTHFUL"

Thus, as it becomes apparent that there is good scientific background as substantiation that aging, at least in some cases, can be accelerated by poor diets, lack of exercise and other stressful lifestyle activities and events, like diseases, and that this accelerated ("premature") aging, at least in some cases, can be slowed and at least some of the effects possibly even reversed by improved nutrition, including improved diet, and possibly improved supplementation, (especially in the case of nutritional deficiencies) as well as including improved (healthful) lifestyle activities and habits (such as exercise, refraining from smoking, caloric restriction).

In light of the scientific evidence that nutritional deficiencies do exist in the general population, improved diet and supplementation can be considered nutritional insurance against at least some types of "premature" (accelerated) aging (as can improved lifestyle habits can be considered insurance against at least some types of accelerated aging).

POINT 2 - THAT THE "STATEMENT IS NOT MISLEADING"

Since accelerated aging is indeed "premature aging", and since providing insurance against premature aging is an anti-aging technique, we propose that the use of the terms, "anti-aging vitamins" and "premature aging", especially with the very present and very clear accompanying disclaimers on the poster and in the accompanying brochure, is not misleading, but rather, brings information to the public in a form that allows us to present the "entire picture" of what the public can do to remove themselves from the higher risk group which will experience accelerated aging from nutritional deficiencies or stressful lifestyle activities that may deplete nutrients.

As you will note, we emphasize that there is no single "magic bullet", but rather that protecting against premature aging is an ongoing multi-faceted lifestyle modification, not unachievable, but definitely requiring a commitment.

INSURANCE TO PROTECT CONSUMERS AGAINST POSSIBLE MISINTERPRETATION

Although we've gone to the effort to clearly elucidate the "disclaimers", we may not cover every possible interpretation. Therefore we employ a strong guarantee to protect the consumer against any misinterpretation on their part. Our guarantee (backed by our 18 years in business in San Francisco with a high profile of integrity, customer service and customer support) is to ensure that if the public tries our "anti-aging vitamin" supplement and subsequently finds that he or she has no use or need for it, they will know they are not at financial risk, and will be confident they are protected by a guarantee from an 18 year old stable company with an excellent reputation for honesty.